

**REMARKS**

This application has been reviewed in light of the Final Office Action dated December 14, 2005. Claims 14-23 are pending in the application. Claims 14 and 19 are amended in a manner that Applicant believes overcome the rejections in the Office Action. New claims 24 and 25 are added. Support for the amendments and new claims can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicant is believed to be entitled. Applicant submits that no new matter or issues are introduced by the amendments. In the present application, claims 1-13 were previously cancelled. Applicant reserves the right to prosecute the subject matter of any cancelled claims in continuing and/or divisional applications.

In the Office Action, claims 14-23 were rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement. The claims have been amended to overcome the rejections. Further, the specification has been amended to include language from commonly assigned U.S. Application Serial No. 09/506,484, now U.S. Patent No. 6,428,517, which was incorporated by reference in the original filing of the present application at page 11, lines 4-7 thereof, to provide additional support for the amended claims. The amended language can be found at col. 2, line 59 through col. 3, line 15, and at col. 3, lines 26-30 of U.S. Patent No. 6,428,517. As such, the amendment to the specification of the present application is material that was previously incorporated by reference and, therefore, this amendment contains no new matter. Accordingly, the claims include subject matter that was described in the specification so as to comply with the written description requirement. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 14-23 were rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the enablement requirement. The claims have been amended to overcome the rejections. Further, the specification has been amended to include language from commonly assigned U.S. Application Serial No. 09/506,484, now U.S. Patent No. 6,428,517, which was incorporated by reference in the original filing of the present application at page 11, lines 4-7 thereof, to provide additional support for the amended claims. The amended language can be

found at col. 2, line 59 through col. 3, line 15, and at col. 3, lines 26-30 of U.S. Patent No. 6,428,517. As such, the amendment to the specification of the present application is material that was previously incorporated by reference and, therefore, this amendment contains no new matter. Accordingly, the claims include subject matter that is described in the specification so as to comply with the enablement requirement. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 14, 15, 17, 19 and 22 of the present application were rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 3,244,172 to Brown (Brown '172). However, it is respectfully submitted that amended independent claim 14, claims 15 and 17 depending therefrom, amended independent claim 19 and claim 22 depending therefrom, clearly and patentably distinguish over the Brown '172 patent.

Referring to the disclosure of the Brown '172 patent, an injection method is described whereby a needle is inserted with a subject to an injection site. The disclosure mentions twisting the needle for entry/removal, however, the disclosure does not teach or suggest advancing and rotating the needle simultaneously.

At the injection site, the Brown '172 patent discloses that an active substance is injected and thereafter an inactive substance is injected while revolving the needle. The needle is not further advanced during the injections. The method described in the Brown '172 patent is directed to slow release of the active substance, not reducing needle deflection to reduce pain.

In contrast, amended claim 14 of the present application recites, *inter alia*, “[a] method of reducing pain in a patient during the administration of a drug with a needle by reducing needle deflection to a patient comprising:...providing a needle ...advancing said needle in a soft body tissue while simultaneously rotating the needle to reduce pain-producing deflection of the needle; and causing said drug to flow through said needle to the tissue as the needle is advanced and rotated.” Amended claim 19 of the present application recites, *inter alia*, “[a] method of reducing pain ... by reducing needle deflection, said method comprising: ...advancing a needle

into a patient soft tissue; simultaneously rotating the needle to prevent the needle from increasing pain by bending within the tissue as it is being advanced; and introducing the drug through the needle into the tissue as the needle is advanced and rotated.”

The Brown `172 patent in no way discloses or suggests a method as recited in amended claim 14 or amended claim 19. The Brown `172 patent does not disclose or suggest, *inter alia*, a needle injection method that reduces pain in a patient during the administration of a drug by advancing a needle in tissue while simultaneously rotating the needle to reduce needle deflection that causes pain. Rather, the Brown `172 patent describes a method directed to slow release of an active substance, not reducing needle deflection to reduce pain.

Because of the above distinctions, it is respectfully submitted that amended independent claim 14, claims 15 and 17 depending therefrom, amended independent claim 19 and claim 22 depending therefrom are patentable and not obvious over the Brown `172 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 14, 15, 17, 19, 22 and 23 of the present application were rejected under 35 U.S.C. § 103(a) over the Brown `172 patent in view of U.S. Patent No. 5,180,371 to Spinello (Spinello `371). However, it is respectfully submitted that amended independent claim 14, claims 15 and 17 depending therefrom, amended independent claim 19 and claims 22 and 23 depending therefrom, clearly and patentably distinguish over the Spinello `371 patent in any combination with the Brown `172 patent.

The Brown `172 patent has been discussed. The Spinello `371 patent discloses a hypodermic syringe apparatus having a needle being advanced at a slow rate.

The Spinello `371 patent in no way discloses or suggests a method as recited in amended claim 14 or amended claim 19. The Spinello `371 patent does not cure the deficiencies of the Brown `172 patent in that the Spinello `371 patent does not disclose or suggest, *inter alia*, a needle injection method that reduces pain in a patient during the administration of a drug by

advancing a needle in tissue while simultaneously rotating the needle to reduce needle deflection that causes pain.

Because of the above distinctions, it is respectfully submitted that amended independent claim 14, claims 15 and 17 depending therefrom, amended independent claim 19 and claims 22 and 23 depending therefrom are patentable and not obvious over the Spinello '371 patent in any combination with the Brown '172 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 18 and 21 of the present application were rejected under 35 U.S.C. § 103(a) over the Brown '172 patent in view of the Spinello '371 patent in further view of U.S. Patent No. 5,938,635 to Kuhle (Kuhle '635). However, it is respectfully submitted that claim 18, which depends from amended independent claim 14 and claim 21, which depends from amended independent claim 19, clearly and patentably distinguish over the Kuhle '635 patent in any combination with the Spinello '371 patent and the Brown '172 patent.

The Brown '172 patent and the Spinello '371 patent have been discussed. The Kuhle '635 patent discloses a biopsy needle and related operation for obtaining tissue samples.

The Kuhle '635 patent in no way discloses or suggests a method as recited in amended claim 14 or amended claim 19. The Kuhle '635 patent does not cure the deficiencies of the Brown '172 patent or the Spinello '371 patent in that the Kuhle '635 patent does not disclose or suggest, *inter alia*, a needle injection method that reduces pain in a patient during the administration of a drug by advancing a needle in tissue while simultaneously rotating the needle to reduce needle deflection that causes pain.

Because of the above distinctions, it is respectfully submitted that claim 18, which depends from amended independent claim 14 and claim 21, which depends from amended independent claim 19 are patentable and not obvious over the Kuhle '635 patent in any combination with the Spinello '371 patent and the Brown '172 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 16 and 20 of the present application were rejected under 35 U.S.C. § 103(a) over the Brown '172 patent in view of the Spinello '371 patent in further view of U.S. Patent No. 4,381,777 to Garnier (Garnier '777). However, it is respectfully submitted that claim 16, which depends from amended independent claim 14 and claim 20, which depends from amended independent claim 19, clearly and patentably distinguish over the Garnier '777 patent in any combination with the Spinello '371 patent and the Brown '172 patent.

The Brown '172 patent and the Spinello '371 patent have been discussed. The Garnier '777 patent discloses a hand drill device having a needle that acts as a drill bit to penetrate hard porous bone to deliver anesthetic. The needle can be rotated during ejection of fluid from the needle at the injection site. The disclosure does not teach or suggest advancing and rotating the needle simultaneously to the injection site, nor is the disclosure directed to a method of reducing needle deflection to reduce pain.

The Garnier '777 patent in no way discloses or suggests a method as recited in amended claim 14 or amended claim 19. The Garnier '777 patent does not cure the deficiencies of the Brown '172 patent or the Spinello '371 patent in that the Garnier '777 patent does not disclose or suggest, *inter alia*, a needle injection method that reduces pain in a patient during the administration of a drug by advancing a needle in tissue while simultaneously rotating the needle to reduce needle deflection that causes pain.

Because of the above distinctions, it is respectfully submitted that claim 16, which depends from amended independent claim 14 and claim 20, which depends from amended independent claim 19 are patentable and not obvious over the Garnier '777 patent in any combination with the Spinello '371 patent and the Brown '172 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 14-25 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicants' undersigned attorney.

Please charge any deficiency as well as any other fees that may become due at any time during the pendency of this application, or credit any over payment of such fees to deposit account no. 50-0369. Also, in the event that any extensions of time for responding are required for the pending application, please treat this paper as a petition to extend the time as required and charge deposit account no. 50-0369 therefor.

Respectfully submitted,

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